

OCT 3 - 2008

K081933

## 510(k) Summary Pursuant to 21 CFR 807.92

1. Submitted By: Avalon Laboratories, LLC  
2610 E. Homestead Place  
Rancho Dominguez, CA 90220
2. Contact: Lee Wirth  
Avalon Laboratories, LLC  
2610 E. Homestead Place  
Rancho Dominguez, CA 90220  
310-603-2147
3. Product: Avalon Elite™ Multi-Port Venous Femoral  
Catheter  
CFR Section 870.4210  
Catheter, Cannula And Tubing, Vascular,  
Cardiopulmonary Bypass  
Class II  
Product Code: DWF
4. Common/Trade Name:  
  
Avalon Elite™ Multi-Port Venous Femoral  
Catheter

### Description:

The Avalon Elite Multi-Port Venous Femoral Catheter is a one piece, wire reinforced cannula with multiple side hole drainage openings proximal to an open tip. The catheter is supplied with a dilator/introducer to facilitate placement into the vasculature by normal access techniques. The introducer/dilator is intended to follow a pre-positioned standard guidewire (not supplied.)

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Avalon Elite™ Multi-Port Venous Femoral Catheter

The cannulae are available in 20 Fr, 22 Fr, 24 Fr, 26 Fr, and 28 Fr sizes. The insertable length is 24 inches [61cm].

The device is supplied sterile, non-pyrogenic and is intended for single use via prescription.

Intended Use:

The Avalon Elite™ Multi-Port Venous Femoral Catheter with Introducer is indicated to drain central venous blood via the femoral vein during extracorporeal procedures for up to six hours.

Technological Characteristics and Substantial Equivalence:

The Avalon Elite™ Multi-Port Venous Femoral Catheter is substantially equivalent to the Bio-Medicus Multi-Stage Venous Femoral Cannula with Introducer (K052524). Device comparisons show both products have similar size ranges, materials, lengths, drainage openings, introducers, and packaging. Both devices are supplied as single use sterile products.

Performance Testing:

The Avalon Elite™ Multi-Port Venous Femoral Catheter was subjected to numerous tests and comparisons to the predicate device. Testing included Pressure/Burst, Simulated Use, Kink Resistance, Tensile Strength, Flow Characteristics, Hemolysis, and Biocompatibility.

Conclusions:

The studies conducted on Avalon Elite™ Multi-Port Venous Femoral Catheters demonstrate that the device is substantially equivalent to the predicate device currently in commercial distribution.

The predicate catheters and the Avalon catheters share similar design, size, and generic materials of construction. Comparisons show that the Avalon products are equivalent to the predicate products in all key areas of features and performance. The indications for use are similar to the indications for

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use of the predicate. Testing under simulated use conditions shows that the Avalon catheter maintains performance after 7 days.



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Avalon Laboratories, LLC  
c/o Mr. Lee Wirth  
Director of Quality Assurance and Regulatory Affairs  
2610 E. Homestead Place  
Rancho Dominguez, CA 90220

Re: K081933  
Avalon Elite™ Multi-Port Venous Femoral Catheter 20Fr, 22Fr, 24FR, 26Fr, 28FR  
Models 11020, 11022, 11024, 11026, 11028  
Regulation Number: 21 CFR 870.4210  
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula and tubing,  
Regulatory Class: Class II (two)  
Product Code: DWF  
Dated: July 7, 2008  
Received: July 8, 2008

Dear Mr. Wirth:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', with a long horizontal flourish extending to the right.

Bram D. Zuckerman, M.D.  
Director  
Division of Cardiovascular Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number: K081933

Device Name: Avalon Elite™ Multi-Port Venous Femoral Catheter

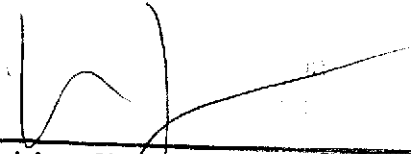
Indications for Use:

The Avalon Elite™ Multi-Port Venous Femoral Catheter with Introducer is indicated to drain central venous blood via the femoral vein during extracorporeal procedures for up to six hours.

Prescription Use X or Over-the-counter use \_\_\_\_\_  
(per CFR 801.109)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
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(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number K081933